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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/652,498	09/02/2003	Randolf Von Oepen	17601.16a.1.1.1	2721

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EXAMINER	
PELLEGRINO, BRIAN E	
ART UNIT	**PAPER NUMBER**
3738	

MAIL DATE	DELIVERY MODE
06/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/652,498	VON OEPEN, RANDOLF	
	Examiner	Art Unit	
	Brian E. Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,8,10,16,21,23,24 and 30-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,8,10,16,21,23,24 and 30-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3,8,10,21,23,24,30-33,35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glastra et al. (EP 0779062) in view of Pinchuk et al. (EP 861638). Glastra et al. show (Fig. 6) a stent-catheter arrangement having a balloon **26** with two fully expandable "substantially cylindrical" sections **27** and a "substantially cylindrical" section of reduced expandability between the expandable sections. The examiner is interpreting the claimed elements "substantially cylindrical" in this way: something that is in the form of a conduit having a hollow or cylindrical like cross-section. Claims in a pending application should be given their broadest reasonable interpretation. *In re Pearson*, 181 USPQ 641 (CCPA 1974). See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054,1055. However, Glastra does not disclose a liquid impermeable cover over the stent or a stiffening element for forming a reduced expandable section. It is noted that Glastra shows (Fig. 6) a flared stent with reduced cross section. Also note the middle section is coupled by tapered sections.

Pinchuk also illustrates (Figs. 8-11) a stent **100** that is flared and can be considered as a substantially cylindrical deformable stent to extend over a balloon catheter. Pinchuk also teaches the stent has a graft (which is well known in the art to be liquid impermeable), col. 7, line 49. Pinchuk additionally teaches (Fig. 11) an

independent stiffening element **105'** can be used to form a section of reduced expandability **106'**. It would have been obvious to one of ordinary skill in the art to use a blood impermeable cover on the stent and a stiffening element as taught by Pinchuk with the stent-catheter system of Glastra et al. in order to provide an outer surface that does not allow blood leakage and to provide a throttle portion to increase blood flow to reduce the likelihood of plaque buildup. Regarding claims 2,3,8,21,35 Pinchuk et al. disclose graft material is a "foil" of body-tolerated material, such as the polymer PTFE, col. 1, lines 48-50. With respect to claims 10,23,24,32,33 Pinchuk also discloses that stiffening the midsection or segments of the apparatus is accomplished by placing rings about the surface of the stent and can be accomplished in a secondary process such as bonding, col. 7, lines 10-16,21-24. Regarding claims 36,37, the flared ends of the stent or "fixing portions" are configured to achieve blood throttling in the vessel and the tapered portions are configured to minimize blood turbulence in the vessel.

Claims 16,34,38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glastra et al. (EP 0779062) in view of Pinchuk et al. (EP 861638) as applied to claim 1 above, and further in view of Crocker et al. (5843116). Glastra in view of Pinchuk is explained supra. However, Glastra as modified by Pinchuk fail to disclose the stiffening elements are within the balloon segments in the reduced diameter section. Crocker et al. show (Fig. 3) that stiffening material is integrated into balloons to limit the expansion of the balloon in certain areas, col. 5, lines 29-49. Crocker also teaches bonding, col. 6, lines 8-10. It would have been obvious to one of ordinary skill in the art to use the teaching of Crocker et al. that stiffening material can be incorporated into balloons and

place the stiffening elements of Pinchuk et al. within the balloon of Glastra such that the elements are non-obtrusive and do not become unattached since Pinchuk taught separate elements. It would be an obvious expedient to eliminate the risk of stiffening elements from detaching during use of the apparatus by integrating them in the balloon.

Response to Arguments

Applicant's arguments filed 3/16/09 have been fully considered but they are not persuasive. First, in considering the term “cylindrical” a definiton would be appropriate to determine what is being defined by the claim and (Philip’s Encyclopedia 2008) defines a cylinder as: Solid figure or surface with straight parallel sides and a circular or oval cross section. However, the Examiner also notes that it is important to consider the feature with the language used to define the element being claimed and when “substantially” is used as a modifier it broadens the scope. For example, since sections of the stent catheter are defined as “substantially cylindrical” it is interpreted as a tubular element that does not have to be exactly circular, and most importantly to note is that it does not require the diameter of the section to remain constant. After reviewing the scope of the claim, a review of Applicant’s specification as to whether any variation is described or does Applicant provide some boundaries or limits to set forth what defines "substantially cylindrical". In this instance, the Applicant provides no description and the drawings only appear to show “substantially cylindrical”. No cross section is illustrated in the drawings to show a clear description of any specific defined cylindrical section. Thus, the broadest interpretation is used and is appropriate. In the absence of an

express intent to impart a novel meaning to the claim terms, the words are presumed to take on the ordinary and customary meanings attributed to them by those of ordinary skill in the art. Now in reviewing the prior art to Glastra in using one example illustrated in Fig. 6, it is seen that the catheter has a balloon with two ends having sections defining these ends with cross-sections of circular or oval dimensions that form cylinders for the stent to reside over. Since Applicant provides no basis in the disclosure to compare the scope outside of what is illustrated in Applicant's drawing, the evaulation of prior art is based on broadest reasonable interpretation. So in reviewing prior art with respect to the claimed feature, it can be seen that the reduced expandability section that is cylindrical is clearly flanked on its ends by tapered sections in the Glastra balloon catheter. It must be noted that the claimed embodiment is not limited to a drawing illustration when the limitations of the claim use relative terminology in the context of technology. The Examiner is entitled to give terms in a claim its plain meaning as interpreted by one of ordinary skill in the art. It is noted that the specification must clearly set forth the definition explicitly and with reasonable clarity, deliberateness, and precision. Exemplification is not an explicit definition. Even explicit definitions can be subject to varying interpretations. See *Teleflex, Inc. v. Ficosa North America Corp.*, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002), *Rexnord Corp. v. Laitram Corp.*, 60 USPQ2d 1851,1854 (Fed. Cir. 2001) and MPEP 2111.01. It appears applicant's argument against the Glastra reference is that the end sections of the balloon catheter are diverging end sections or funnel-shaped ends that are alleged to not be "substantially cylindrical" end sections. However, in stating Glastra fails to show certain features of

applicant's invention, it is noted that the features upon which applicant relies (i.e., constant cross-section end sections) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant is advised that a specification must provide proper antecedent basis for any claim terminology whether originally filed or subsequently added to the claims. Also note that the term "section" is a broad limitation with no set dimensions and can arbitrarily defined by a large or small dimension to define a section.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738